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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,364	07/05/2001	Paul D. van Poelje	030727.0037.CIP1	7049

36183 7590 12/01/2004

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,364	VAN POELJE ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cov r sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2004 and 14 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-114* is/are pending in the application.

4a) Of the above claim(s) *6-10,19 and 46-114* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-18 and 20-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's response (remarks/Arguments) filed on August 17, 2004 and September 14, 2004 wherein no amendment is filed, i.e., no claims are amended, cancelled, or newly submitted.

Currently, claims 1-114 are pending in this application.

Claims 1-5, 11-18, and 20-45 are currently under examination on the merits.

It is noted that Claims 46-114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention; Claims 6-10 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species, of record in the previous Office Action dated February 17, 2004. The claims have been examined insofar as they read on the elected specie.

Information Disclosure Statement (IDS)

Applicants' IDS submitted November 12, 2003 is acknowledged and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11-18, and 20-45 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the

particular compounds having the particular formula herein as FBPase inhibitor in combination with glyburide and other particular agents as insulin secretagogue, employed in composition herein, does not reasonably provide enablement for co-administering any compounds represented by a FBPase inhibitor and an insulin secretagogue recited in the claims herein, for the same reasons of record stated in the Office Action dated February 17, 2004.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a pharmaceutical composition for treating diabetes in a mammal.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the instant claims read on any compounds represented by a FBPase inhibitor and an insulin secretagogue employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case, "represented by a FBPase inhibitor" and "an insulin secretagogue", recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides those particular compounds for each kind of functional compounds for the composition.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide

those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co*. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a mammal, the ***combination*** of any compounds represented by a FBPase inhibitor and an insulin secretagogue, which may encompass more than a thousand compounds. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible

drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would not be able to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compounds for each kind of functional compounds employed in the composition herein is disclosed in the specification. It is noted that only one particular combination of Compound J and glyburide, was tested and is shown in Example X at page 315-316 of the specification. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does

not demonstrate criticality of a claimed range of the active agents or compounds in the claimed composition. See MPEP § 716.02(d).

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Response to Argument

Applicant's arguments filed August 17, 2004 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement have been fully considered but are not deemed persuasive as further discussed below.

It is the examiner's position that Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)), as pointed out in the previous Office Action.

Applicant argues that the novelty of the invention is not either an FBPase inhibitor or an insulin secretagogue, but the point of novelty is the combination of these two agents. Applicant's arguments are not found persuasive and convincing since the point of novelty is the combination of the two agents, **both represented by functional languages**. Hence, the functional languages in the claims are employed as the essential and critical elements of the claimed invention.

Claims are given their **broadest** reasonable interpretation. In this case, the instant claims are **not** limited to those particular compounds having the particular formula herein as FBPase inhibitor in combination with glyburide and other particular agents as insulin secretagogue in the specification. On the contrary, the instant claims read on administering to a patient the ***combination*** of any compounds represented by a FBPase inhibitor and an insulin secretagogue.

"Applicants believe that a person of ordinary skill in the art could determine which compounds are FBPase inhititors through the use of routine experimentation, such as described in Examples A and B". Applicant also asserts that "With the use of

high-throughput screening, there is nothing undue about the amount of experimentation needed to determine what compounds are encompassed by the claims".

Contrary to Applicant's assertion, these functional recitations may reasonably encompass those known and **unknown** or **future known** compounds having the recited functions as of the instant filing date. Note that those **future known** compounds have not yet been discovered and/or made as of the instant filing date. Hence, those unknown or future known compounds encompassed by claim 1 herein **must** require to additional or future research to discover, establish, make and/or verify their usefulness, for example, including "with the use of high-throughput screening". Therefore, as indicated in the previous Office Action, the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

As pointed out in the previous Office Action, *Genentech*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (emphasis added).

Note that Applicant own research paper is seen to support the examiner position herein, undue experimentation involved herein (see Erion et al. Book of Abstracts, 219th ACS National Meeting, San Francisco, CA, March 26-30, 2000 (2000), COMP-029. American Chemical Society: Washington, D. C.):

> AB "Drug discovery efforts targeting nucleotide binding sites have largely failed due to difficulties in finding ligands with high binding affinities, good enzyme specificities, and suitable cell penetration

properties. The poor success is attributed primarily to two reasons. First, ligands with high binding affinities usually require a neg. charged group and therefore have limited cell penetration. Second, ligands with high enzyme specificities are rare and difficult to design due to the structural similarity of nucleotide binding sites and their high abundance in nature. In an effort to bypass these challenging design hurdles and identify nucleotide mimetics that bind to the AMP site of fructose 1,6-bisphosphatase, we calcd. the relative binding free energies for 15 AMP analogs using free energy perturbation methodol. and the human FBPase-AMP structure. Calcd. binding free energy differences were in good agreement with the relative inhibitory potencies detd. exptl. The results of the study suggest that free energy calcns. are useful for characterizing nucleotide binding sites and identifying interactions that are essential for high binding affinity and specificity". (emphases added)

Thus, Applicants clearly acknowledge and understand the difficulties and poor success in finding suitable drug candidates. Let alone the ***combination*** of any compounds represented by a FBPase inhibitor and an insulin secretagogue, encompassed by the claims, i.e., those known and **unknown** or **future known** compounds.

It is noted that only **one** particular combination of Compound J and glyburide, was tested and is shown in Example X at page 315-316 of the specification.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search and

undue experimentation for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

As discussed in the previous Office Action, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (i.e., a mammal) the ***combination*** of any compound represented by the functional languages. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed, 1996) page 51 in particular. In the absence of fully recognizing the identity of the members genus herein, one of skill in the art would not be able to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional property herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

For the above stated reasons, said claims are properly rejected made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement. Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the same reasons of record stated in the Office Action dated February 17, 2004.

The expression "**M** " in claim 11 renders claims 11 and 13 indefinite. The expression "**M**" is not understood since "M" is not defined in the formula I. Therefore, the scope of claims is indefinite as to the structural formula encompassed thereby.

Response to Argument

Applicant's arguments filed August 17, 2004 with respect to this rejection made under 35 U.S.C. 112, second paragraph, for indefinite recitation have been fully considered but are not deemed persuasive as further discussed below.

Applicant asserts that "The term "M" is defined functionally in claim 11 in that "wherein in vivo or in vitro compounds of formulae I and IA are converted to M-PO_3^{2-} which inhibits FBPase". Contrary to Applicant's assertion, one of ordinary skill in the art could not ascertain and interpret the **metes and bounds** of the patent protection desired as to what "M" encompassed thereby, which may reasonably encompass widely varying groups.

Given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions. Therefore, the scope of claim is indefinite as to the composition encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 11-18, and 20-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasibhatla et al. (WO 98/39342, WO 98/39343, and WO 98/39344, PTO-892) and Melchior et al. (ANNALS OF PHARMACOTHERAPY, (1996 Feb) 30 (2) 158-64, PTO-892), for the same reasons of record stated in the Office Action dated February 17, 2004.

Kasibhatla et al. (WO 98/39342, WO 98/39343, and WO 98/39344) discloses that the instant particular compounds for example having the formula 1 in WO 98/39342, the formula 1 in WO 98/39343, and the formula 1 in WO 98/39344, being FBpase inhibitors at the AMP site, are useful in a composition and a method of treating diabetes in a mammal. See WO 98/39342: abstract, page 1 lines 5-10, page 5-15-47 and claims 1-53; WO 98/39344: abstract, page 1 lines 5-10, page 6-36 and all claims therein; WO 98/39343: abstract, page 1 lines 5-10, page 6-75, and all claims therein.

Melchior et al. teaches that the particular insulin secretagogue, sulfonylureas such as glyburide, is well known to be useful in a composition and in the treatment of diabetes in a mammal. See the abstract in particular.

The prior art does not expressly disclose that the employment of the particular FBpase inhibitor of Kasibhatla et al. in combination with particular insulin secretagogue, sulfonylureas such as glyburide in a composition for the treatment of diabetes.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular FBpase inhibitor of Kasibhatla et al. in combination with particular insulin secretagogue, sulfonylureas such as glyburide in a composition for the treatment of diabetes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular FBpase inhibitor of Kasibhatla et al. in combination with particular insulin secretagogue, sulfonylureas such as glyburide in a composition for the treatment of diabetes since both the particular FBpase inhibitor of Kasibhatla et al., and particular insulin secretagogue, sulfonylureas such as glyburide are known to be useful in a composition and a method of treating diabetes in a mammal based on the prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the particular FBpase inhibitor of Kasibhatla et al. in combination with particular insulin secretagogue, sulfonylureas such as glyburide both known useful for the same purpose, i.e., treating diabetes, would improve the therapeutic effects for treating the same diseases, and/or would produce additive therapeutic effects in treating the same.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third

composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Argument

Applicant's arguments filed August 17, 2004 with respect to this rejection made under 35 U.S.C. 103(a) in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that "The cited art does not suggest that a combination of insulin secretagogues and FBPase inhibitors will result in any additive effect. A person of ordinary skill in the art would not randomly combine agents that show improved glycemic control and expect that such a combination would be successful".

Applicant's argument has been considered but is not found persuasive. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

In the instant case, as discussed in the set forth 103(a) rejection above, both the particular FBpase inhibitor of Kasibhatla et al., and particular insulin secretagogue,

sulfonylureas such as glyburide are known to be useful in a composition and a method of treating diabetes in a mammal based on the prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the particular FBpase inhibitor of Kasibhatla et al. in combination with particular insulin secretagogue, sulfonylureas such as glyburide both known useful for the same purpose, i.e., treating diabetes, would improve the therapeutic effects for treating the same diseases, and/or would produce additive therapeutic effects in treating the same, absent evidence to the contrary.

Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11-18, and 20-45 are provisionally rejected rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims of copending Application No. 09/470649, for the same reasons of record stated in the Office Action dated February 17, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to COMBINATION OF FBPASE INHIBITORS AND INSULIN SENSITIZERS FOR THE TREATMENT OF DIABETES.

The claim of the instant application is drawn to employ the same FBpase inhibitor in combination with insulin secretagogue, such as sulfonylureas, e.g., glyburide in a composition for the treatment of diabetes. Thus, the two compositions in the copending Application and the instant Application are seen to substantially overlap.

Thus, the instant claims 1-5, 11-18, and 20-45 are seen to be obvious over the all claims of copending Application No. 09/470649.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument

Applicant's arguments filed August 17, 2004 with respect to this rejection made under 35 U.S.C. 103(a) in the previous Office Action have been fully considered but are not deemed persuasive as further discussed below.

Applicants argue that the agents claimed in the copending Application and the present Application for in treating diabetes operate by different mechanisms. However, the particular insulin secretagogue, sulfonylureas, e.g., glyburide, would be reasonably interpreted as an INSULIN SENSITIZER FOR THE TREATMENT OF DIABETES, as claimed in the copending Application. Thus, the two compositions in the copending Application and the instant Application are seen to be obvious to each other.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
November 19, 2004